PSJ2 Exh 106



OBJECTIVES

- Drug Trends
- DEA/Regulatory Compliance
- Drug Loss Investigations
 - → Monthly counts Importance
 - Suspected Loss
 - → DEA Form 106
 - DUR Reports
 - Audit Spreadsheets
 - Information not included
 - Ethics Point Entry subpoena
 - Partnership PDM/APDM/HR



OBJECTIVES

- **CSMP**
 - → Corresponding Responsibility
 - → PDMP
- Pharmacy Robbery
- Combat Methamphetamine





DRUG DIVERSION

- Definition
 - Use of any prescription drug for recreational purpose
- Happening every day
 - → Many ways
 - → All neighborhoods
 - → Workplace



THOUGHT PROCESS

- Patient is prescribed the controlled substance
 - → Dental surgery
 - → Sports Injury
- Patient thinks it's ok being prescribed
- Pharmacy dispenses the medication
- Does not realize it becomes addicting

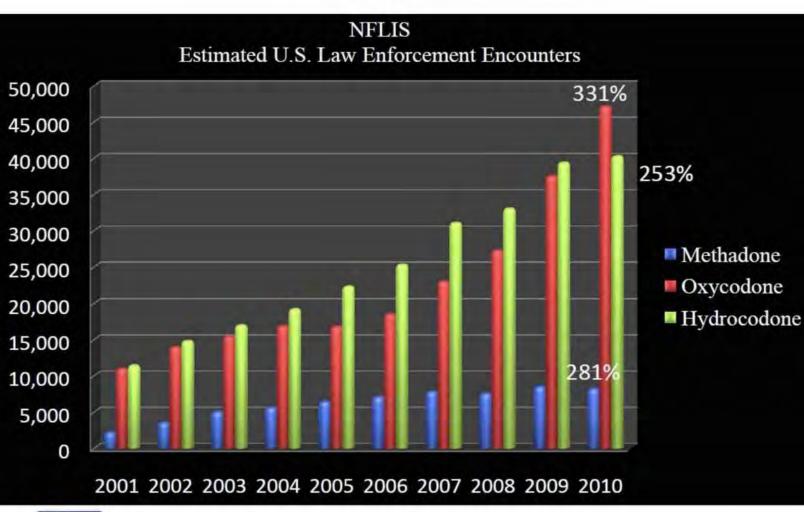


PRESCRIPTION DRUG ABUSE

- Declared an epidemic
- More Americans abuse prescription drugs than the number of:
 - → Cocaine
 - → Hallucinogen
 - → Heroin
 - → Inhalant abusers

COMBINED







TOP ITEMS FOR DRUG DIVERSION

- Opiods Hydro's/Oxy's
- Pseudoephedrine
- Dextromethorphan
- Depressants alprazolam
- Stimulants amphetamine/methylphenidate
- Muscle relaxants carisoprodol, cyclobenzaprine



HYDROCODONE

- #1 prescription drug sold in the U.S.
 - → Hydrocodone/APAP
 - → Lipitor
 - → Amoxicillin
 - → Lisinopril
 - → Simvastatin
- 99% of the worlds hydrocodone is in the U.S.
- ▶ 131,200,000 prescriptions sold for hydrocodone in 2010



OXYCONTIN

- Extended release
 - → Larger doses of oxycodone than the IR formulation
- Street Value: \$80 per 80mg tablet





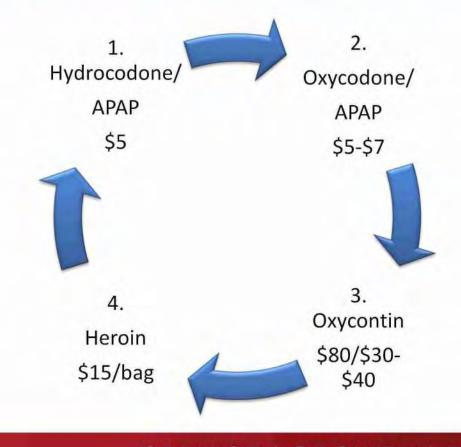
ALPRAZOLAM (Z-BARS)

- Preferred
 - → Rapid onset
 - → Longer duration
- Ranked #3 in number of controlled substance prescriptions dispensed from 2003-2006





DRUG ABUSE CYCLE



With us, it's personal.

CLOSED DISTRIBUTION SYSTEM

- Controlled Substances Act of 1970
 - Closed System of Distribution to prevent diversion
 - → Must be registered with the DEA to lawfully handle controlled substances
 - → Ultimate users are not required to register with the DEA to posses controlled substances



CLOSED DISTRIBUTION SYSTEM

- Ultimate User lawfully obtained for his own use
- Reverse Distribution
 - → Stores cannot take prescription drugs back from a patient
 - → Offer Take Away Box for sale
- Law Enforcement may receive controlled substances from ultimate users
 - → Drug Take Back Days
 - → Drug Drop Off Boxes

CONTROLLED SUBSTANCE RECORDKEEPING

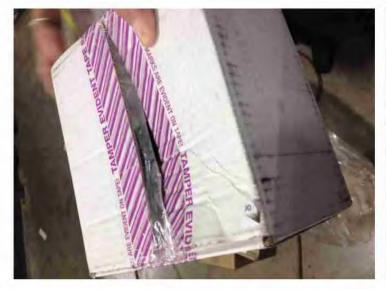
- Reverse Distributer Reports
 - → Automatically prints in the pharmacy
 - → Pharmacist matches their controlled outdate transfer to the report
 - → Verify quantities
 - → File in corresponding tab
- Store to Store transfers
 - → Must contain sending and reverse
 - → If a controlled substance is transferred store to store a copy of the transfer detail must be filed in the controlled substance recordkeeping box



PACKAGING

Reusing ANDA Boxes

- Clear tape over already tampered "Tamper Resistant Tape"
- Enables opening and resealing of packages in 1 motion.





PACKAGING/LABELING

Multiple Labels

- Old ANDA shipping label was not removed
- All other Retailers are using black and white labels
 - · Rite Aid's labels are blocked out with blue
 - Easily identified







THE TRANSIT PROCESS

How do our packages hold up during the FedEx transit process?

- 1st Picture
 - Bottles were not closed tightly
 - Evident that pills were loose in the box
 - Bubble wrap was not used for glass bottles
 - Medication syrup was leaking from the package
- 2nd Picture
 - Syrup leaked as the package was pulled off the belt





THE TRANSIT PROCESS

How do our packages hold up during the FedEx transit process?

- ▶ 1st Picture
 - 1 Fluzone Vial packaged in a 16"X10"X9" RX Returns Box without any fillers
- ▶ 2nd Picture
 - 1 CII item packaged in a 8"X8"X8" RX Returns Box without any fillers
 - · Box was crushed during the transit process
 - Enabled easy access to the package or the item potentially getting lost in transit





4.

TAPE

The technique and adhesiveness of the security tape

- Pictured on the top row
 - The security tape is not very adhesive
 - Can easily open the box without any evidence of tampering
- Pictured on the bottom row
 - Left 1 strip of tape to secure the package resulted in an open package
 - Right 2 strips of tape, 1 on each side of the flap. Left a large gap down the center of the package









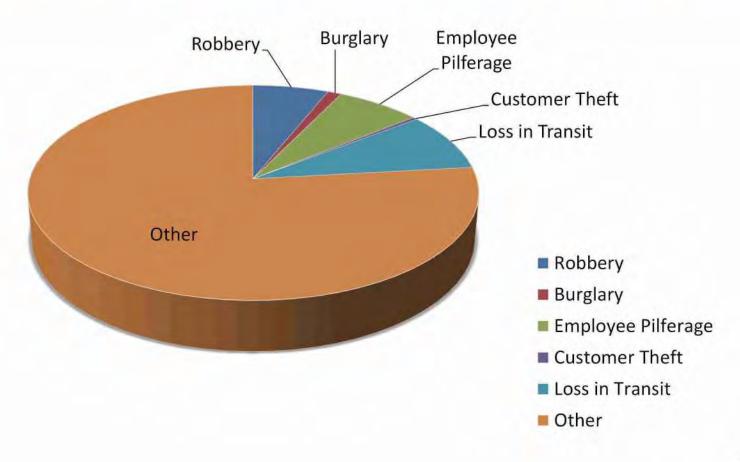
POTENTIAL SOLUTIONS

- Remove "MedTurn" name from label.
 - → Replace with "MT"
- Change to 3 Day Express
 - → Boxes/Bags provided free via FedEx
 - · More secure and less likely to get tampered with.
- Eliminate use of security tape
 - → Easily identifiable
 - → Comes off easy.
- Additional barcode to identify controls



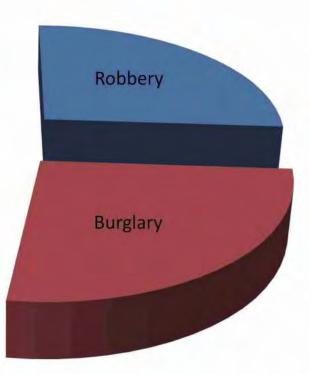


DEA 106 – BY NUMBER OF INCIDENTS

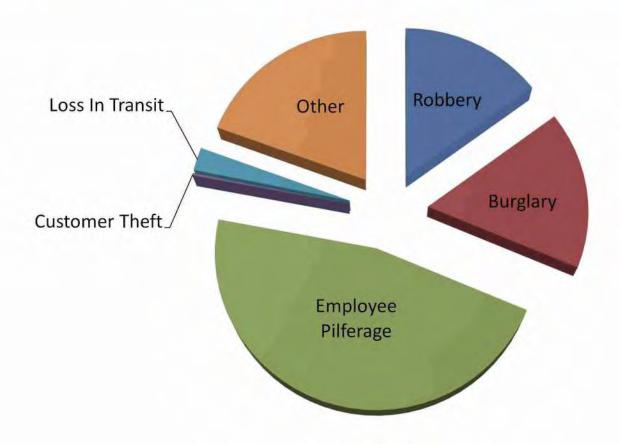


DEA 106 – BY DOLLAR VALUE





DEA 106 – BY DOSAGE UNITS



CONTROLLED SUBSTANCE THEFT AND LOSS

Notify DEA

Immediately upon discovery of a theft of significant loss of controlled substances, a pharmacy, as required by regulation, must contact the nearest DEA Diversion Field Office by telephone, facsimile or by a brief written message explaining the circumstances. If there is a question as to whether a theft has occurred or a loss is significant, a registrant should err on the side of caution and report it to DEA.



DEA FORM 106 PROCESS

- Potential Loss
 - → PIC identifies a discrepancy
 - →APDM notified of NaviScript Inventory Case opened from corporate
 - → Hotline tip
 - **→**Local Police Report
 - → Potential diversion



DEA FORM 106 PROCESS - PARTNERSHIP

- PDM / APDM must partner together!
 - →Preliminary investigation to confirm a potential loss
 - Confirmed no loss within 24 hours = no suspected loss
 - Confirmed loss within 24 hours = suspected loss
 - Cannot confirm no loss within 24 hours = suspected loss



DEA FORM 106 PROCESS – SUSPECTED LOSS FORM

PDM completes a Suspected Loss Form and faxes to the local DEA office and Pharmacy Board

within 1 business day

NOTE: APDM/DM can complete in PDM absence



DEA FORM 106 PROCESS – SUSPECTED LOSS FORM

Send (fax/email) a copy of the Suspected Loss Form & DEA fax receipt confirmation to

Andrea Bucher and to your RVP/RxVP and APDM







SUSPECTED CONTROLLED SUBSTANCE LOSS DEA Notification

DIVISION 2

Door Agent in Chargo:

The Filte Aid pharmacy listed below has identified a suspected loss, if we confirm the suspected loss as actual, we will initiate a loss prevention investigation and notify the local police department and state regulatory agency. We will submit a DEA-100 cnce we have gathered adequate information about the actual loss. If you have any questions concerning this suspected loss or the outcome of the preliminary audit, or if you would like to assist in this investigation, please contact the Pharmacy District Manager listed below.

Data of Suspected Loss: Details

Pita Aid Pharmacy Stone e: Telaphone: DEA Number:

Stone Address:
Pharmacy District Manager:
Address:
Office Telaphone: Cell Phone:
Loss Preversion Manager:

DEA Offices Covering Rife Aid Division 2

DEA Office	Area/State Covered	Fax Number	DEA Office	Area/State Covered	Fax Number
Detroit	Michigan	313-226-7545	New York	NY minus Buffalo/Long laland	212-337-1536
Cincinnati	Southern DH	513-684-3080	Long Island	Long Island	801-420-4551
Clievaland	Northern DH	216-554-1307	Boston	Massachusetts	-517-557-2126
Columbus	Central/Southern OH	014-459-5788	Manchester	ME/NH	500-529-7488
Petsburgh	Wastern PA	412-777-1880	Providence	Rhoda Island	401-732-3310
Philadelphia.	Dalawara/Eastorn PA	215-238-5170	Hartford	Connecticut	860-257-2615
Buffalo	Wastern/Central NY	718-843-2154	Charleston	West Virginia	304-347-5212
Abany	Alberry area	518-782-2068	Newark	Northern/Dentral NJ	973-775-1100
Burington	Vermont	802-951-2970	Atlantic City	Atlantic City/SW NJ	509-383-0664
Camdan	Southarn NJ	850-321-2437			

Board of Pharmacy	Fax Number	Board of Pharmacy	Fax Number	
Otio	814-752-4638	Massachusetts	617-973-0963	
West Virginia	304-558-0572	Vernvorit	802-629-2455	
Michigan	517-241-5072	Rhode Island	A01-022-2108	
New Jersey	873-648-3356	Connecticut	880-713-7242	
New York	518-473-0995	New Hampshire	603-271-2850	
Maino	207-624-9637			

NOTE: Plasme lax is copy of the SUSPECTED LOSS FORM and DEA has receipt confirmation to Fits Aid Corporate/Janual Hart at 717-975-3760 and your FMRMP and is copy of the suspected loss form to the LPM.

SUSPECTED LOSS FORM

- Suspected Loss Form triggers a reminder program
 - →14 / 21 / 28 day reminder
 - → At 28 days the issue is heightened to Vice President Pharmacy Operations



INVESTIGATION

- An investigation should be completed within 28 days
- PDM and APDM must work together to develop an action plan and begin a drug loss investigation



NO LOSS

If after an investigation no loss is discovered, the form can be updated and re-faxed to the DEA / Board to close the file



COMPLETE CONTROLLED SUBSTANCE AUDIT

- PDM or designee <u>MUST</u> complete an audit for all controlled substances
 - →CII, III, IV & V (NO EXCEPTIONS)
- Establish a starting date and an ending date for the audit period



WHY A COMPLETE PHYSICAL COUNT?

- Official results to the Board/DEA
 - →Especially with theft by a registered individual
- Results to police/prosecutor for their case
- Designated official records for accountability
- Protect the associates in the pharmacy



DRUG UTILIZATION REPORT

- Request reports and populated spreadsheet to complete the audit
 - →Andrea Bucher

 - •



REPORTS INCLUDE:

- Summary or detailed DUR's
- McKesson purchases
- ANDA purchases
- Rite Aid distribution center purchases
- MedTurn return report
- Store to store transfers





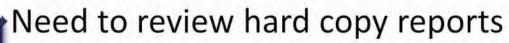
GCN ROLL UP CODES

- GCN roll up codes are included on the second tab of the audit spreadsheet
- This identifies all NDCs associated with a specific roll up code
 - → For example: Oxycodone/APAP may include Endocet/Percocet
 - → Package sizes will also be grouped



REPORT DATA

- Several factors may impact spreadsheet data:
 - →When truck was received in the pharmacy
 - Pick date versus delivery date
 - →Was count at start or close of business
 - · Impacts sales data
 - → Was start/end count completed properly
 - → Acquisition data must be entered by PDM
 - →Form 106's filed during audit period must added





AUDIT RESULTS

- Review spreadsheet with hard copy reports to determine a loss
- Never report overages
- Balance within a drug type (hydrocodones)
- Exercise professional judgment
 - → Remember Class III-V drugs are estimated values except select hydrocodone/alprazolam products



DRAFTING DEA FORM 106

- Draft the Form 106 for <u>any</u> discrepancy or shortage
- NOTE: Only controlled substances are placed on the back page of the Form 106
 - → No Viagra/Cialis

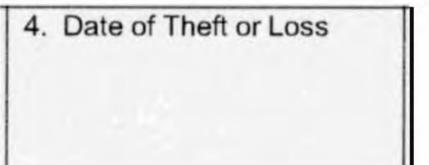


REPORT	OF THEFT OR LOSS	OF CONTROLLE	D SUBSTAN	CES	
Federal Regulations require registrants to sui Enforcement Administration. Complete the front and back of this form in Retain the triplicate copy for your records.	omit a detailed report of any theft or	loss of Controlled Substa	ances to the Drug	OMB APPROVAL No. 1117-0001	
1. Name and Address of Registrant (Include ZIP)		100000000000000000000000000000000000000	2. Phone No.	(Include Area Code)	
		ZIP CODE			
3. DEA Registration Number	4. Date of Theft or Loss	5. Principal Business	of Registrant (Check or	ne)	
2 ttr. prefix 7 digit suffix		1 Pharmac 2 Practition 3 Manufact 4 Hospital/	ner 6 urer 7	Methadone Program	
County in which Registrant is Located Ye Ye	e? 	phone Number of Police De	epartment (include Are	a Code)	
	Type of Theft or Loss (Check one	and complete items below	v as appropriate)		
		Employee Pilferage Customer Theft	5 Other (Exp	ilain) nsit (Complete Item 14)	
1. If Armed Robbery, was Anyone:	12. Purchase value			pharmaceuticals or	
Killed? No Yes (How many)	controlled sub-	stances taken?		ise taken?] Yes (Est. Value)	
Injured? No Yes (How many)	\$		\$		
4. IF LOST IN TRANSIT, COMPLETE THE FOLI	OWING:				
Name of Common Carrier	B. Name of Consignee		Acceptance of the Property Control of the T	A Registration Number	
Was the carton received by the customer?		E. If received, did it appear to be tampered with?		F. Have you experienced losses in transit from this same carrier in the past? No Yes (How Many)	
15. What identifying marks, symbols, or price coo		19640	ME (10) 200 (Service Community (Community Community Communi	
6. If Official Controlled Substance Order Forms	50 - 1988 P. S. (1985) 50 P. (1	AND AND DESCRIPTION OF THE PROPERTY OF THE PRO			
7. What security measures have been taken to p	prevent future thefts or losses?				
PRIVACY ACT INFORM UTHORITY: Section 301 of the Controlled Subs URPOSE: Report theft or loss of Controlled Subs OUTINE USES: The Controlled Substances Act special reports required for statistical and and information from this system are made to the for purposes stated: A. Other Federal law enforcement and regulat and regulatory purposes. 5. State and local law enforcement and regula md regulatory purposes. FECT: Fallure to report theft or loss of controll FFECT: Fallure to report theft or loss of controll	tances. Act of 1970 (PL 91-513), intances, authorizes the production of ficial purposes. Disclosure of illowing categories of users for the pry agencies for law enforcement tory agencies for law enforcement ed substances may result in	required to respond to a valid OMB control numb collection of information collection of information response, including the	a collection of informa ber. The Valid OMB of h is 1117-0001. Public h is estimated to avera time for reviewing ins pathering and maintain	c reporting burden for this age 30 minutes per structions, searching hing the data needed, and	
penalties under Section 402 and 403 of the	PANNE IN-TIPE IN METABORITH SCHOOL			CONTINUE ON REVERSE	
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BOX 4. - DATE OF LOSS

- Date of loss is the first date any discrepancy was identified
- Typically same date as Suspected Loss Form
 - → Not the audit date range





BOX 7. – PD NOTIFIED?

Police Notified - Yes





BOX 9. – NUMBER OF THEFTS

- 24 months can be provided by Government Affairs
 - → Andrea Bucher 717-731-6545
 - Number of Thefts or Losses Registrant has experienced in the past 24 months



BOX 12. – PURCHASE VALUE

AWP of missing controlled substance

12. Purchase value to registrant of Controlled Substances taken?

\$



BOX 17 – MOST IMPORTANT BOX

- Box 17 is the most important box on the form
- Must have appropriate action for the type of loss
- Is there a cost to the action?
 - → Installing cameras and dvrs in the biometric safe feasible?
- Must address this action with pharmacy manager and pharmacy staff
- ▶ 30/60 day confirmations all are responsible
- 17. What security measures have been taken to prevent future thefts or losses?

Trade Name of Substance or Preparation	NDC Number	Name of Controlled Substance in Preparation	Dosage Strength	Dosage Form	Total Quantity Lost or Stolen Express Quantity in Dosage Units, or Milliliters for Liquids
Demerol	00409-1181-30	Meperidine Hydrochloride	50 mg/ml	Vial	150 ml
Robitussin A-C	00031-8674-25	Codeine Phosphate	2 mg/cc	Liquid	5676 ml
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Sign and Print Name Title Date

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APPROVAL THROUGH GOV'T AFFAIRS

Fax a copy of draft Form 106 to:

Andrea Bucher Government Affairs

and to RxVP/APDM



DEA REPORTING

- Non report threshold quantities
 - → 30 CII dosage units
 - → 100 CIII V dosage units
- NOTE: A form 106 must be drafted and faxed for approval
- Closing a form as a "Non Report" must be authorized by Government Affairs
- All thefts are reported! Even 1 tablet



DEA REPORTING

- PDM to make changes and fax final form to local DEA office, Board of Pharmacy and Drug Control/OPD
- Fax a copy of the final Form 106 and DEA <u>Fax</u> <u>Receipt Confirmation</u> to Government Affairs, RVP/RxVP and APDM to close file
 - NOTE: Process should take ideally two weeks!
- Original sent to the local DEA office



STATE FORMS

- NY State specific reporting form (OPD)
- NJ state specific reporting form (Drug Control)
- NH Pharmacy Manager responsible for filing
 - → Must complete within 14 days



DEA REPORTING

- PDM / APDM must work to identify the source of the loss and close the file (supplemental 106 if needed)
- Once file is closed the local DEA office and Board should be notified of the outcome.
- A copy of the Form 106 and all supporting documentation should be filed in Controlled Substance Record Keeping Box
- Results discussed with Pharmacy Manager and staff (Accountability)





DEA CHECKLIST

- The DEA Checklist identifies all record keeping requirements for compliance with DEA Rules/Regulations
- Invoices
- > 222 Forms
 - → MedTurn must add store's DEA number to the form
- Power of Attorney
- Inventory documents Monthly/May 1





TEAMWORK

- Example:
 - → Case Opened by Profit Protection Analyst 4/2012
 - Possible loss of ~4,000 dosage units
 - → Suspected Loss filed 6/2012
 - → Extension requested for filing DEA 106 7/2012
 - → Filed Form 106 8/2012 Ongoing investigation
 - → Reported loss over 16,000 dosage units
 - → DEA Agents contacted PDM within an hour of the 106 being filed, prompted a visit to the store
 - → No suspects, No admission, DEA not happy



TEAMWORK

- Example:
 - → PDM was informed of a suspected loss by a RXM
 - → PDM did not verify the loss & did not notify the APDM
 - → The RXM conducts their own investigation
 - → Loss was confirmed a week later, pharmacist was terminated
 - → Suspected loss was never filed in a timely manner



TEAMWORK

- PDM/APDM Partnership
 - → Notify each other of the suspected drug loss immediately
 - Ethics Point Case
 - Hotline Tip
 - Associate Tip
 - · Other...
- Critical element of any drug loss investigation
 - Subject Matter Expert PDMs
 - → Tools



APDM NOTIFICATION RESPONSIBILITIES

- All drug loss investigations notify the following:
 - → Divisional AP Director
 - Director Pharmacy Loss Prevention, Sophia Lai
- All pharmacist investigations
 - → Drug loss or other
 - → Sophia Lai
- Email or Phone Call



- Immediate entry into the case management database
 - Suspected drug loss investigations
 - Every suspected loss filed by the PDM should have a corresponding case entry
 - If not opened Ryan Duval will generate a case for you
 - → Robberies
 - → Burglaries
 - Internal investigations
- Drug loss investigations are an APDM's highest priority!
- → Not just a loss to the company Regulatory Implications



- Pending drug loss cases
 - → Weekly updates at minimum
- Closing drug loss cases
 - → Should be done promptly
 - All required fields need to be populated



- Official Record of the Investigation
 - → Mandated by several Boards of Pharmacy
 - May be subpoenaed by the DEA or other regulatory agencies
- Case entry must be
 - → Timely (Retroactive entries NOT ACCEPTABLE)
 - → Accurate (Incomplete entries NOT ACCEPTABLE)
 - → Professional
 - → Proper case documentation guidelines



A COMPLETE CASE ENTRY CONTAINS THE 5W'S & 5C'S

- ▶ 5W's
 - →Who
 - → What
 - →Where
 - →When
 - → Why
 - →How

- ▶ 5C's
 - → Completeness
 - → Conciseness
 - **→**Clearness
 - → Correctness
 - →Courteousness (Be Fair & Objective)

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TOOLS

- Remember 1st step in any drug loss investigation should be to determine if we actually have a loss.
 - →The source?
 - May impact how you proceed in this regard
 - · Example:
 - An anonymous tip that a store associate is stealing drugs
 - Case opened by the corporate data mining team



TOOLS

- Confirm a loss
 - → Corporate data mining
 - Purchase versus Dispensed (PVD) reports.
 - If you have some idea of what drug(s) are missing your analyst can quickly run these reports
 - Up to 13 months
 - Advantage Fast, emailed within a few minutes
 - Disadvantages
 - Drug specific, not effective in cases where no specific drugs have been identified yet
 - Does not take into consideration amount of product currently on the shelf



PURCHASE VS. DISPENSING REPORTS

GCSN	003775	STORE	02/93		
NDC	Description			DEA Code	Pkg Size
00009009	001 XANAX 1	MG TABLET		4	100
00603212	928 ALPRAZO	LAM 1 MG TABL	ET	4	500
59762372	101 ALPRAZO	LAM 1 MG TABL	ET.	4	100
59762372	103 ALPRAZO	LAM 1 MG TABL	.ET	4	500

Begin Date: 5/23/2010 End Date: 8/14/2010

Tru ID	Aud Trn Qty			
CYCLE CNT MTHLY C2	-1338	DC RETURN	-3	
CYCLE COUNT	-1782	TRANSFER IN	500	
DC RECEIPT	6500			
MCKESSON RECEIPT	2000			
TOTAL DISPENSED	5176			



- Confirming a loss continued
 - → Drug Utilization Review (DUR)
 - Most Accurate way to determine a loss
 - Identify what drugs are missing
 - First Step Controlled drug count
 - Covert counts!
 - · Partner with your PDM to request from Andrea Bucher
 - Reconcile



Confirming a loss – continued

DUR

Advantages

- Accurate
 - Assuming beginning and ending counts are accurate
 - Official method for reporting drug loss quantities to the DEA

Disadvantages

- Slow
 - Requires a count to be completed 1st
 - Order reports and lag time to receive
 - → Reconciliation PDM
 - Turnaround time could be days or weeks
 - Beginning counts unreliable = unreliable result

- Confirming a loss continued
 - → Hybrid Approach
 - Data Analysts
 - Navi Inventory
 - PVDs
 - Make an initial determination in order to move on your case
 - Proceed with the DUR to lock in your losses with greater accuracy
 - →Once a controlled drug loss is reasonably confirmed the PDM must file a Suspected Loss form within 24 hours



- Confirmed loss Next Steps
 - → Start with the Data
 - Data Mining Partners!!!
 - Cycle count information (Who's doing the counts?)
 - Ordering Information (Who's ordering or adjusting the orders?)
 - Patient Profiles (APDMs do not access partnership)
 - Audit Trails (Who touches the script and what type of activity?)
 - Removes w/o deletes
 - Deleted script activity
 - PVD reports
 - POS data
 - McKesson Supply Management Online (SMO) reports, etc.



- Confirmed loss Next Steps
 - → Cameras?
 - Overt Location already has cameras? Can it be repositioned for the target area?
 - Covert Needs to be COVERT
 - Partner with a licensed pharmacist (PDM) in that state
 - After hours install
 - Limit knowledge of the case and install to the fewest people possible
 - Great time to get covert counts



- Cameras
 - → Great tool but only as good as the process in which it is used
 - Am I covering the right location?
 - Am I covering all involved locations?
 - Is my DVR power supply backed up?
 - How much video can I realistically review at one time to look for concealment?
 - Minimize time frame is critical SHIFT COUNTS



- Shift Counts
 - → Obtain regular counts on your targeted drugs to limit the timeframe of loss
 - At LEAST once a week
 - PREFERABLY more frequently
 - How much video can you realistically view to try to find your problem? 2 days or 2 weeks?
 - Must be obtained covertly
 - After hours with a licensed PDM partner is ideal
 - Can I trust some in the store to do my counts?
 - Bad Idea
 - » Have you ruled them out as a suspect? How?
 - » Can you count on them counting discreetly? How?



- What if I do not have cameras?
 - → Shift counts can still "lock it in for you"
 - Use your tools Infinium/Kronos, Mckesson reports, Cycle counts, etc.
 - → Who worked on the days or in the timeframes product disappeared?
 - → Who placed the orders?
 - → Were the drugs cycle counted down after the loss?
 - → Who did those counts?
 - Look for the patterns



- The Interview
 - Discuss the strength of your case with your AP Director before the interview
 - → AP Director may also ask you to partner with the Director, Pharmacy Asset Protection
 - →PDM as a subject matter expert and witness where needed in interviews
 - Be prepared to react either to admission or no admission



- Admission obtained
 - → Written Statements
 - → Zero Tolerance Policy
 - → APDM report to Law Enforcement
 - → PDM report to the Board of Pharmacy
- No Admission
 - → Report to Law Enforcement?
 - → Drug Testing?



- What about drug testing? Where does it fit?
 - → Generally our last resort in a drug loss investigation
 - Ineffective if the suspect has or can produce evidence of prescribed target medication testing will be negative
 - · Savvy suspects can purge urine on short notice
 - Many suspects simply walk out or quit rather than test
 - May stop our losses but can't be sure
 - · Some suspects are stealing for sale rather than use



- Drug Testing continued
 - → Legalities
 - Limited in what, if any, testing we can do in certain areas. Ex.
 Vermont
 - Human Resources is currently reviewing our policies and legalities involved
 - → To have any chance of being effective
 - Must be unanticipated
 - Comprehensive
 - Include all who had access to the pharmacy
 - → Last Resort



 Valuable from a due diligence perspective when all else has failed or to confirm we have dealt with our issue completely

- Other tools
 - → Alarm Records/Pharmacy Key Log
 - After hour access to the pharmacy?
 - Rule out FE involvement
 - → Bag Checks APA or member of management
 - Advantage catch the suspect in the act
 - Disadvantage Can be a one shot deal. If the suspect does not get caught on the bag check they may now be alerted to your investigation
 - → Surveillance APA or other
 - Advantage catch suspects in the act
 - Disadvantage requires some knowledge of who and how theft is being perpetrated. Can be costly



- Remember!
 - → Every case is unique
 - → The approach you use may vary from case to case but the basic guidelines are the same
 - Partner with your AP Director
 - Partner with your Director, Pharmacy AP
 - Partner with your Profit Protection Analysts



FORM 106

- DEA Form 106 is to be filed on all controlled drug losses
- Can be done at the conclusion of the investigation as long as it could be concluded within 28 days of the suspected loss filed
 - → If needed can file a supplemental or amended 106 at the conclusion
- PDM (with guidance from Government Affairs) is responsible for filing the DEA Form 106



- Case 1
 - → PDM Johnson receives a tip from an associate that one of the techs at store 123 is stealing drugs.
 - → PDM Johnson reaches out to APDM Smith
 - →APDM Smith contacts his Profit Protection Analyst to review Naviscript Inventory to see if any losses may be out there
 - Profit Protection Analyst finds suspicious activity involving hydrocodone



- Profit Protection Analyst runs PVD reports
 - → 3, 6, 9 month timeframes on all strengths of hydrocodone
 - → Emails it to the APDM reflecting potential losses
 - → Also sees ordering activities/data of interest and forwards additional detailed information also
- PDM and APDM make arrangements to go into the location AFTER HOURS Thursday night to get full counts for DUR reports and install cameras
- Only the PDM, APDM and DM are aware



- PDM obtains DURs and reconciles the counts
 - → Reveals significant losses of several drugs
 - · Hydrocodone, alprazolam and Suboxone
- PDM files suspected loss form
- PDM and APDM are going in AFTER HOURS every few days to get fresh counts and reconciling to determine if new losses occur



- PDM confirms a new loss
 - → 200 hydrocodone 10/325 are missing within a 4 day window
- PDM and APDM go in after hours to pull/replace DVR
- APDM reviews video and finds 2 incidents of concealment
- APDM partners with AP Director to discuss proceeding to interview, AP Director ok's interview plan



- APDM and PDM partner to arrange interview including coverage needed to keep location staffed, PDM present as witness and SME
- APDM obtains admission and written statement
- Final Due Diligence Final Counts and DUR
 - → DEA 106 Filed?
 - →Interviews on remaining staff?
 - → Any disciplinary action involving other associates/management?



- Investigation without any validation
 - → APDM reacts to a source without any due diligence to confirm there's an actual loss
 - Result hours of time wasted on a fruitless chase
- "Blowing our Cover"
 - → APDM or PDM compromise the investigation by doing things that alert RX staff that an investigation is in progress.
 - Trusting a store associate with facts of the case
 - Doing a "covert" install in the middle of the day
 - Result Drug losses stop for now and investigation fails to produce a suspect.
- Note: We are now facing regulatory challenges/fines for failing to surface/solve drug losses

- Not utilizing all available resources
 - → APDM does not contact Profit Protection Analysts
 - Misses opportunity to obtain additional evidence to support the investigation
- Relying too much on cameras
 - →APDM does a covert install and nothing else figuring he can get concealment on video
 - There are many ways to steal which may appear as normal activity on video



- Jumping to interview too soon
 - →Imperative to discuss your case with your AP Director prior to the interview
 - → Your AP Director has the knowledge and experience to determine if your case is ready
- Reliance on Drug Testing to solve your case
 - → Very few (possibly none) admissions and/or arrests for drug theft are made solely based on positive drug test.



- Failure to escalate issues with the investigation
 - → If your case is being delayed or compromised by someone/something outside your control you must escalate to your AP Director right away.
 - → Failure to enter the case and/or facts into Ethics Point timely



INTERVIEWS/STATEMENTS

- APDM responsible for conducting the interviews
- APDM responsible for obtaining documentation of the interviews
 - → Rite Aid Letter of Explanation
- Statement should include answers to the 5W's



INTERVIEWS/STATEMENTS

- Only correct factual errors
 - Employee should draw a ling through the error and initial the change
 - → Do Not correct spelling or grammar
- Page's must be numbered and initialed by the employee
 - → Protects us
- Questions regarding proper documentation should be directed to your Divisional or Regional AP Director



INTERNAL DRUG LOSS CASES

- Drug losses caused by associate theft
 - → Misappropriation Drugs
 - → Priority over cash/mdse loss
- Zero Tolerance Policy
 - → All associates identified as being responsible for controlled drug theft are to be arrested or reported to law enforcement – NO EXCEPTIONS!
 - → BOP Licensed Associate (intern, tech or pharmacist) are to be reported to the board NO EXCEPTIONS!
- ▶ This must be documented in the case entry as completed



EXTERNAL DRUG LOSS CASES

 Drug losses caused by vendor theft, customer theft or an unidentifiable origin are to be entered into Ethics Point



PDM RESPONSIBILITIES

- Completion and submission of the Suspected Loss Form (DM/APDM could complete if PDM is not available)
- Notifying the APDM of any potential drug losses
- Reconciliation of controlled drugs
- Completion and submission of the Form 106
- Assisting the APDM with the investigation
 - → Camera installs, shift counts, witnessing interviews
 - → Must be licensed in the State the store is in
- Administering the disciplinary action (partner with HR)
- Notification to the BOP where applicable

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APDM RESPONSIBILITIES

- Notifying PDM of any potential drug loss cases
- Conducting the investigation (partnering with PDM)
- Documentation of the case
- Conducting interviews, obtaining statements, civil restitution documents
- Recommendation on disciplinary action
- Contacting law enforcement where applicable





SPARE PHARMACY KEYS

- Kept in Rx Security Envelopes
 - → Tamper evident
 - → Unique security code
 - → Opaque but still visible
 - Alarm codes/Safe Codes MUST be folded

Rx Security Envelope Example (SKU 0461461 1=10)



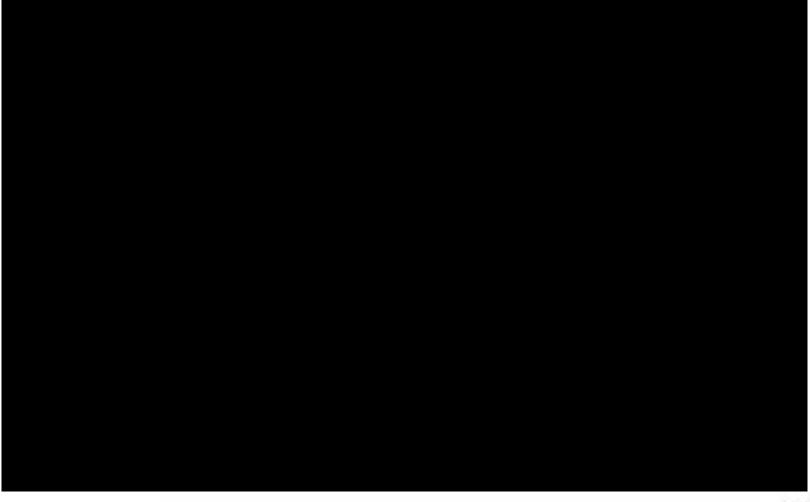
104

SPARE PHARMACY KEYS

- Rx Key Log
 - → Document security information from the Rx Security Envelope
 - → Kept in FE Manager's office



MANDATORY RX KEY LOG



106

SPARE PHARMACY KEYS

- Pharmacist Closing Responsibilities
 - → Log unique security code
 - → Sign and date in the "Close" section of the log
 - Give the completed log and sealed envelope to FE Management to place in the safe
 - States with lock boxes pharmacist should place in the sealed envelope in the lock box after completing the log.



SPARE PHARMACY KEYS

- Pharmacist Opening Responsibilities
 - → Obtain the Key log and Rx Security Envelope from FE Management
 - Access the lock box in states that require
 - → Verify
 - Properly sealed
 - Security code matches the previous "Close" entry
 - → Log unique security code
 - → Sign and date in the "Open" section of the log



SPARE PHARMACY KEYS

- Validation
 - → The security code for the last "Close" entry must match the envelope.
 - → Envelope must be intact
 - If envelope is open, compromised or does not match the log contact your PDM or APDM IMMEDIATELY.



PHARMACY SECURITY

- Unauthorized Access
 - → APA's
 - → FE cashiers
 - → Vendors
 - McKesson Drivers
 - →When a licensed pharmacist within the State is not present



PHARMACY SECURITY

- No unauthorized associates
- Associates performing proper job functions
 - → NJ/Technician/Cashier
 - · Several thefts of CDS by cashiers
 - Appearance before NJ Board of Pharmacy to discuss losses related to cashier thefts
 - Outline Rite Aid policy so compliance must be 100%.





MONTHLY CONTROLLED DRUG AUDIT

- Must physically count
 - → All Cll's
 - CII Perpetual Inventory Log must be updated with monthly counts
 - → Top 6 strengths of hydrocodone
 - → Top 4 strengths of alprazolam
- Pharmacy Manager and/or staff pharmacist must notify their PDM immediately if there is a suspected or know loss or theft of controlled substances.





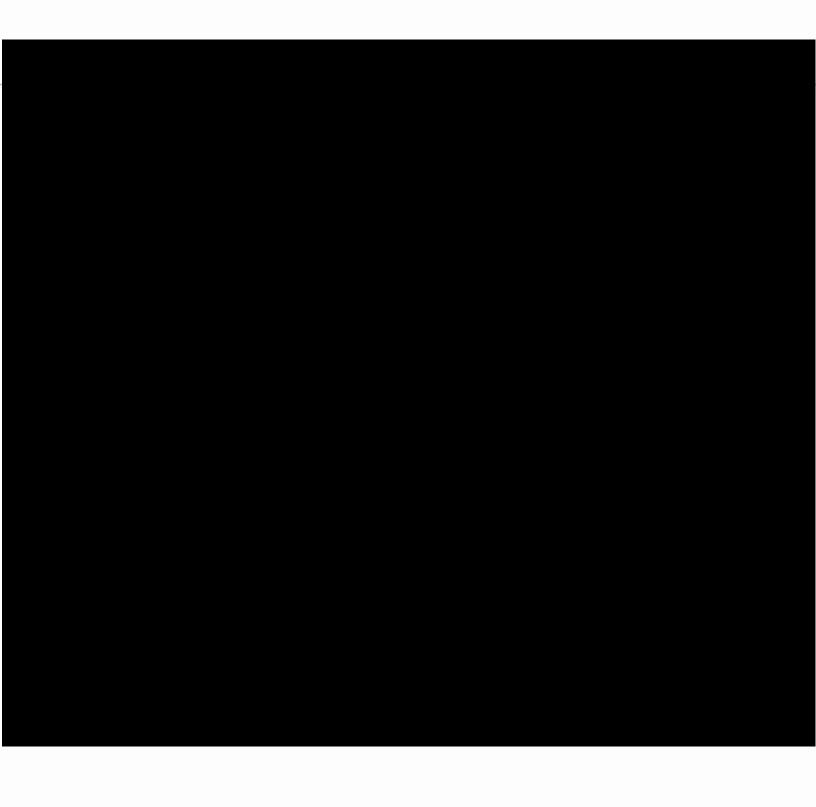








Case: 1:17-md-02804-DAP Doc #: 2423-5 Filed: 08/15/19 120 of 167. PageID #: 402493





Case: 1:17-md-02804-DAP Doc #: 2423-5 Filed: 08/15/19 123 of 167. PageID #: 402496

WHAT DO YOU DO?

Subject: Count off on Generic Soma 350 (Control Substance)

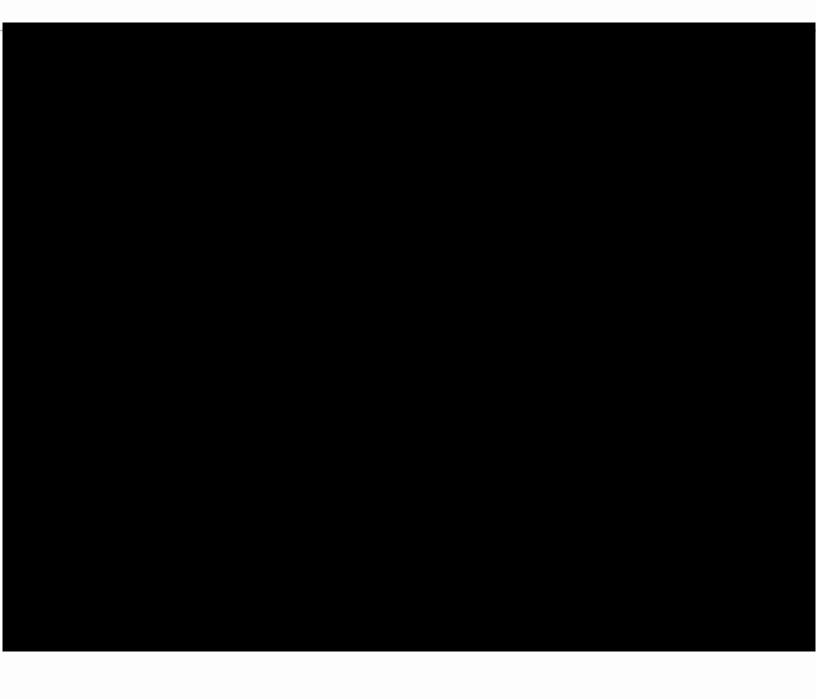
System says we have 140 of NDC 00603-2582-21.

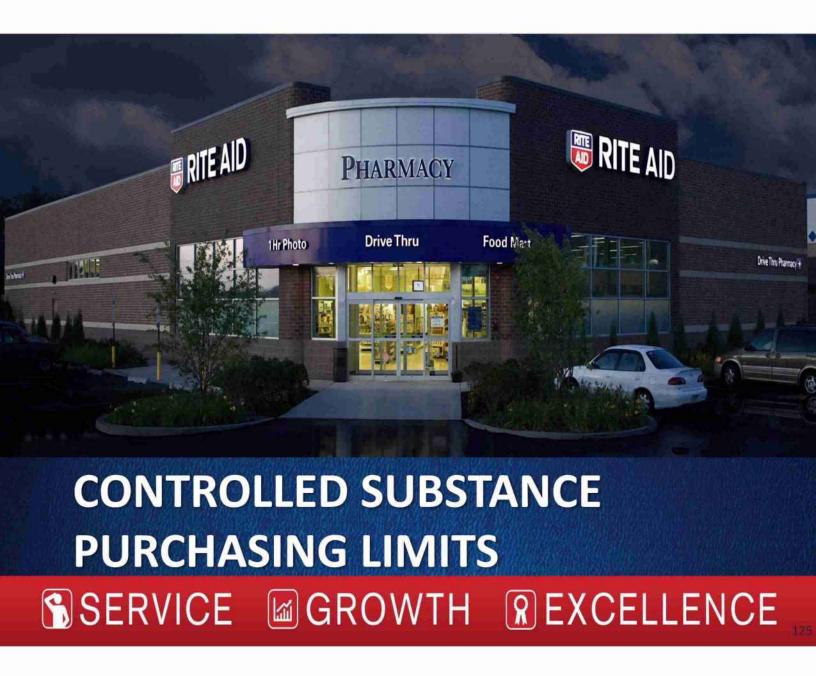
We only have 85 in stock.

Should I update the system?

I had to MCK some for tomorrow for a patient (after doing a 1 day partial).







MCKESSON CSMP

- **▶** CSMP
 - → Controlled Substance Monitoring Program
 - → Designed to meet DEA reporting requirements
 - Establishes thresholds for purchases of controlled substances
 - Based on individual pharmacy's movement history



MCKESSON THRESHOLDS

- Established per calendar month
- Individual Base Code
 - → "active ingredient"
 - → Any dosage form of the base code
 - · Store reached their threshold for Diazepam
 - The store would be blocked from ordering any diazepam containing product for the remainder of the calendar month
 - Includes any strength/dosage form
 - Can reorder the next month or if an increase is approved



MCKESSON THRESHOLDS

- Based on the highest month's movement in the last 12 months
 - Highest number of units purchased in a calendar month
 - → Plus 15% for CIII-V and 50% for CIIs
- This is only McKesson purchasing data (NOT DC)
- Threshold limits are based on the date the medication was ordered
 - →Place an order on 1/31 will be subject to the January threshold even though the store will not receive until February



THRESHOLD ACCOMMODATIONS

- Warehouse item out of stock
 - McKesson will be advised to adjust the threshold to accommodate our business needs
- New Stores
 - Data will be based on surrounding stores ordering trends
- Acquisitions
 - Adjusted based on acquisition data



ORDER VOLUME

- Place smaller more frequent CII orders
 - → Avoids problems with the threshold
 - → Reduces risk of diversion/robberies/burglaries
 - → No more than a 2 week supply



ALERTS

- Pharmacy notification
 - → Pass 75% of their threshold for the base code
 - → Message on their invoices
- Thresholds can be adjusted for individual base codes
 - → Requires legitimate business reasons
 - → Requires approval from the PDM
 - → Coordinated corporately through AP



PDM ACTION FOR THRESHOLD INCREASE

- McKesson customer service will advise the pharmacist to contact their PDM for adjustment approval
- PDM must send a written communication to the Director, Pharmacy AP



PDM ACTION FOR THRESHOLD INCREASE

- Include in the communication
 - → Store number
 - → Base code (active ingredient)
 - → Reason for the adjustment
 - New pain clinic etc. will need prescribing MD data for review
 - → Requested adjustment percentage
 - Copy RXVP on communication
- Upon approval/denial the PDM will be notified
 - → PDM should notify the pharmacy



DISTRIBUTION CENTER THRESHOLD

- Threshold limits
 - →5,000 dosage units of any controlled substance NDC/week
 - → PSE 24 packages of any UPC/week
- DC threshold increases
 - Written communication to Janet Hart or Andrea Bucher
 - → Same criteria as McKesson threshold increases
 - Store number, controlled substance item, reason for the increase, quantity adjustment



LEGITIMATE REASON?

Subject: RE: oxycodone

other pharmacies in the area refusing to fill these rxs for pts. i call and verify scripts are legit. drs and pts are out of state. we are the only rx in dc,md,va who will fill their rxs. increase in rxs. drs are charles kessler, enrique gonzalez-pujol, and john mirczak. the increase isnt necessarily in rxs for these medications but qty. pts come in with rxs for #180 at a time. we will be losing a chance to capitalize on these rxs every month if we cant keep the medication in stock.



THRESHOLD INCREASE?

I am sending this email as we haven't heard anything regarding increasing our threshold at Mckesson for our pain managment customer that was previously using Franks pharmacy. We have decided to move forward to help this customer. We will need to be able to supply him MONTHLY with the following meds: Oxycodone soln 20mg/ml-5 bottles, oxycod/apap 5/325-#360, oxycodone 5 mg tabs-#600, oxycontin 80mg # 90, dronabinol 5 mg # 20 and also he will need Brand name Dilaudid 4mg #1000 every 8 days. We will need to have the medications in stock by the end of this month and be able to continue to reorder. Not sure if we should reorder the Dilaudid upon dispensing every 8 days or if we should do that monthly with the rest. Please let us know ASAP as we need to let the customer know so he may plan accordingly. Our concern going forward is that Mckesson will stock what we need and we will not be limited in our order quantity as we reorder. Please let me know as well as our other 3 rph as we are here on different days.



DEA ACTIVITY

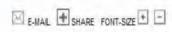




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DEA Serves Suspension Order On Walgreen Distribution Center In Jupiter, Florida

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Consequences

9/15/2012 4:58 PM ET

Order to Walgreen (WAG: Quote) Distribution Center in Jupiter, Florida. The order bars Walgreens Jupiter from handling controlled substances including oxycodone and hydrocodone, pending a judicial proceeding.

The Walgreens Jupiter is one of twelve distribution centers owned and operated by the Walgreens Corporation in Deerfield, Illinois, which is also the parent company to more than 7800 Walgreens retail pharmacies in the United States. The Walgreens Jupiter distributes controlled substances exclusively to its own Walgreens pharmacies located on the east coast of the United State, including the state of Florida.

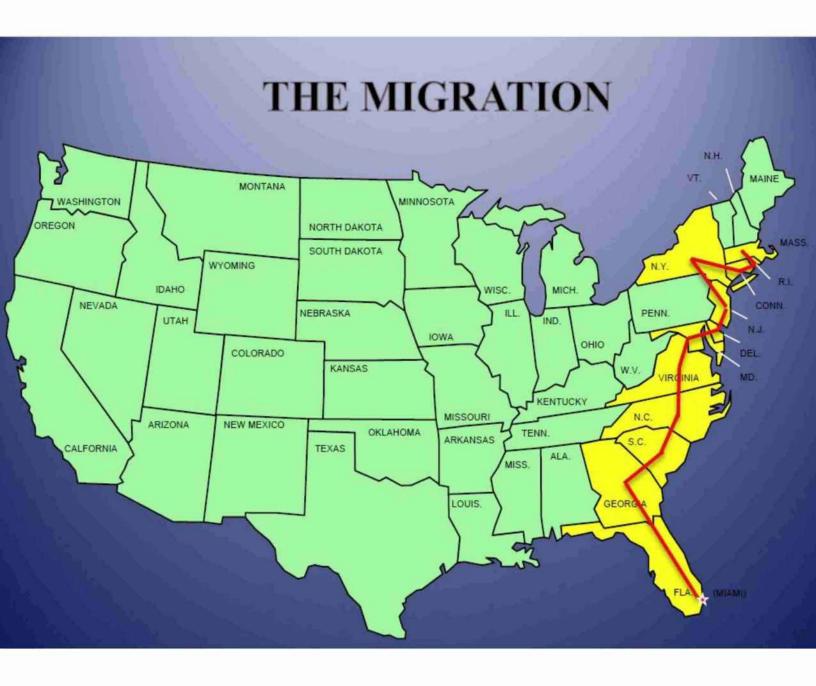
Since 2009, Walgreens Jupiter has been the single largest distributor of oxycodone products in Florida. At about the same time as the abuse of prescription drugs became an epidemic in Florida, Walgreens' Florida retail pharmacies, supplied by Walgreens Jupiter, commanded an increasingly large percentage of the oxycodone business, the DEA said on Friday.

Oxycodone is a Schedule II controlled substance which is highly addictive and known to be highly abused and diverted in the state of Florida.

Post-Debt Crisis, On April 4, 2012, the DEA Miami Field Division served an Administrative Inspection Warrant or AIW on Waldreens

American Pain: The Largest U.S. Pill Mill's Rise

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CFR 1306.04 (A)

A prescription for a controlled substance to be effective <u>must be issued for a legitimate</u> <u>medical purpose</u> by an individual practitioner acting <u>in the usual course of his professional</u> <u>practice.</u>



CFR 1306.04 (A)

The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.



CFR 1306.04 (A)

- An order purporting to be a prescription issued not in the usual is not a prescription within the meaning and intent of section 309 of the Act course of professional treatment (21 U.S.C. 829); and
- The person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances



PHARMACIST'S CORRESPONDING RESPONSIBILITIES

- Geographical distance between the Dr. and the patient or between the pharmacy and the patient
 - → Would you fill a prescription for a patient that resides in Ohio, prescribed by a physician in Florida at a Rite Aid in Massachusetts?
 - → NO



PHARMACIST'S CORRESPONDING RESPONSIBILITIES

- Validate the prescription
 - → Is contacting the prescriber's office and receiving a confirmation that the prescription was written by the prescriber sufficient in the previous scenario?
 - → NO



THE TRINITY/HOLY TRINITY

Is there a legitimate medical reason for a patient to be prescribed an opiate, a benzodiazepine and carisoprodol?





PDMP

- Encourage pharmacists to check the PDMP in available states
- Accessible through the Rite Aid Portal
- Check if there are "Red Flags"
 - Is the patient in the geographic area of the pharmacy
 - → Is the prescriber known to the pharmacy
 - → Has the patient been on a controlled substance for more than 12 weeks
 - Is there suspicious activity
 - Early refills
 - Large quantities
 - Cash



REPORT SUSPICIOUS ACTIVITY

- Your pharmacists should report these trends to the PDM
- ▶ PDM
 - → Conduct a store visit
 - → Gather information
 - → Doctor detailing?
 - → Report to Government Affairs
 - Deaths/OD
 - File Net Claims



CLINIC PROTOCOL

- Upon a second request for a threshold increase
 - → Clinic Protocol will be sent to PDM and APDM
 - Verify prescriber and credentials
 - Verify physical location of the clinic/office
 - Take pictures of exterior and interior of office COVERTLY
 - · Review prescribing patterns
 - Contact local DEA/BOP/Medical board to inquire about complaints/issues/concerns
 - Deemed clinically appropriate



CLINIC PROTOCOL

- Deemed clinically appropriate
 - → Assess the volume of new business generated
 - → Review security of the pharmacy
 - → Determine thresholds
 - →Applicable documentation being proper obtained and handled within all state/federal laws and regulations
 - → Quarterly completion of DEA checklist
 - → Review clinic and standards every 6 months





PREVENTION TIPS

- G.E.T. Greet customers as they enter your pharmacy.
 - → Be aware if they are wearing masks, hoods, latex gloves, etc.
- Be aware of your surroundings
- Controlled safes/cabinets must be locket when not in use
- Keep pharmacy doors locked at all times
- Never leave the pharmacy area unattended



PREVENTION TIPS

- Wipe counters and front doors
 - → Finger prints
- Mark your bottles
 - → RA and store number
 - Provides a link for law enforcement





DURING AN EVENT

- Primary concern
 - → Safety of coworkers and customers
- Do not resist
- Remain calm no sudden movements
- Cooperate and follow instructions given by the robber
 - Do exactly what you are told, nothing more, nothing less, do not argue
- Make mental notes of the robber hair, clothing, shoes, tattoos, scars, etc.
- Do not attempt to apprehend the criminal



POST ROBBERY EVENT

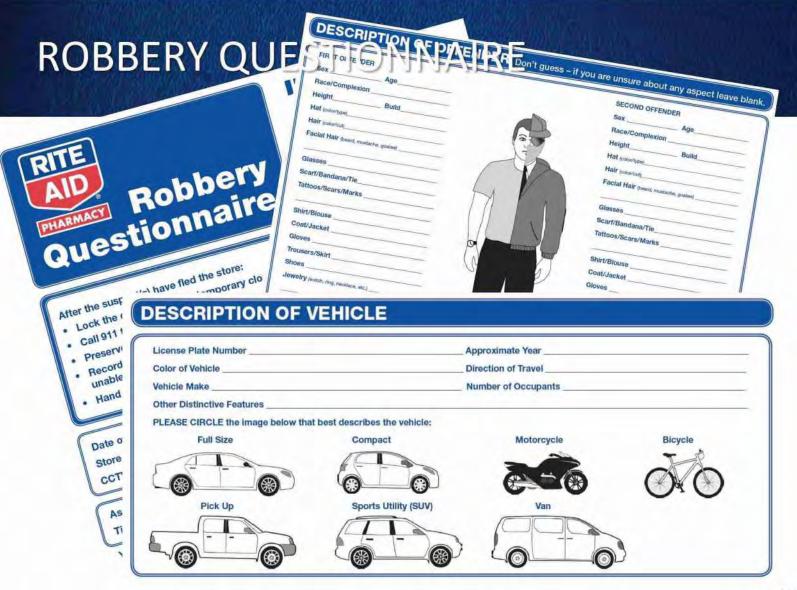
- Lock the front doors
 - Prevent re-entry of the robber
- ▶ Call 911
- Immediately get treatment for anyone that maybe injured (Within limits of ability)
- Protect the crime scene
 - Don't touch anything and stop others from touching
- Call the DM/PDM/APDM
 - → DM/PDM/APDM contact RVP/RXVP/AP Director
- Obtain names and phone numbers of customer witnesses if possible



POST ROBBERY EVENT

- Write everything down robbery questionnaire as soon as possible
 - Don't compare notes before completing, get individual accounting
 - → Don't rely on memory
- Do NOT stop or review surveillance video until speaking to the APDM
- Notify HRM coordinate assistance (EAP)





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POST ROBBERY EVENT PDM RESPONSIBILITIES

- Get an accounting of items stolen
- File a suspected loss form if controlled substances are taken
 - → Follow up with a 106 form



POST ROBBERY EVENT APDM RESPONSIBILITIES

- Ensures crime scene is secured properly, if not already done
- Update Asset Protection Director throughout investigation
- Coordinates investigation with police:
 - → Obtain written statements from associate witnesses
 - Secure copy of any surveillance recordings
 - → Take photographs of the scene when necessary
 - Identify losses in funds, merchandise, or property damages
 - Follow-up with assigned police investigator(s) until case is solved
- Case entry into Ethics Point





PSEUDOEPHEDRINE

- Class I Chemical
- Must be behind the RX counter
 - → Secured when RX department is closed
- Must utilize license capture
- Data to Meth Check (& DEA)
- Data for law enforcement (portal/Alycia Pote)
- Must report significant thefts to the DEA
 - Not on a Form 106, simply a letter stating the circumstance of theft or loss of PSE



PSEUDOEPHEDRINE TRANSACTIONS

- Can you detect a suspicious transaction?
 - → Customers arrive as a group
 - Each purchases PSE products up to the transaction limit
 - Customers attempt to purchase up to the transaction limit on the same day and/or repeatedly within a few days
 - Frequent MethCheck rejections
 - Buy only the largest package size available
 - → Can't pronounce pseudoephedrine
 - → Traveling long distances to buy PSE out of State Driver's License or ID
 - → Expired/damaged /defaced government issued ID

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PSEUDOEPHEDRINE TRANSACTIONS

- Buys in the same transaction
 - Alcohol
 - Drain cleaner
 - Rock salt
 - Lighter fluid
 - · Coffee filters
 - Matches
 - Wears an I love crystal meth t-shirt
- → Pays cash





WHAT CAN YOU DO IF YOU SUSPECT A SUSPICIOUS PSE TRANSACTION?

- Deny the Sale
 - → Responsibility to deny the sale if you feel it is not for a legitimate reason
 - → Cannot profile indicators
 - → Cannot solely rely on MethCheck
- Product Placement
 - → Moving PSE product out of customers view
 - → Work with PDM on product placement
- ▶ Report Suspicious Activity to PDM/APDM
 - Investigate



ASSOCIATE RESPONSIBILITIES

- Must ensure customer ID's are valid
 - → Match photo
- Scan ID
 - → Manually inputted data must be accurate
 - ZZZZZZZZZZ
 - VVVVVVVV
- Do not place returned PSE on shelf for resale
- Properly handling requests from law enforcement on PSE sales information.

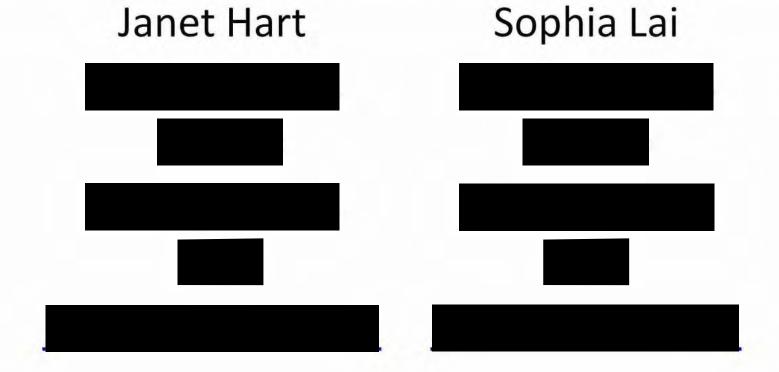


QUESTIONS?





GOV'T AFFAIRS/ASSET PROTECTION



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Notes Summary:

Slide 115: 'Suggest strongly that the stores print the work sheet prior to staring the inventory. Full and partial packages are reported.' Slide 143: 'Bad doctors/Pill Mills

Patient resides in the geographical area of the pharmacy

Prescriber is familiar to the pharmacist

Other medications on the profile - maintenance meds/medication history Form of payment

Frequency - early refills

Significant quantities prescribed - MD's and Rph's responsible for OD's Do not call the number on the prescription, call the prescriber's number on file in NexGen - fake doctors PDMP'